

REMARKS/ARGUMENTS

Applicants have amended the claims to recite more clearly and distinctly the claimed subject matter. These amendments do not narrow the scope of the claims and are fully supported by the application as originally filed. Entry of the amendment and favorable reconsideration are respectfully requested.

Claim Rejections under 35 U.S.C. § 112 ¶ 1

The Office Action rejected all claims under consideration for allegedly lack of enablement under 35 U.S.C. § 112, first paragraph. The Office Action states that it is not clear how the disclosed method results in the claimed nano-composite. Applicants respectfully disagree. The specification, from example at page 5, lines 14 to 27, and in Example 1, clearly describes how a nano-composite of the present invention is obtained. Specifically, the composite of the invention is obtained by centrifuging the solution containing the bio-self-assembled collagen and calcium phosphate composite, freeze-drying the precipitates and grinding into fine powder. When observed under a transmission electron microscope, the powder has a multiple laminar structure having periodically repeated units (see also Fig. 1A). There is simply no basis to argue that an ordinarily skilled person in the art would have to undertake undue experimentation to practice the fully described method, and there is no reason whatsoever to doubt that the method will not result in the claimed nano-composite.

Thus, it is respectfully submitted that the rejection of Claims 1-3 for lack of enablement is improper. Reconsideration and withdrawal of the rejection are respectfully requested.

Claim Rejections under 35 U.S.C. § 112, ¶ 2

The Office Action rejected Claims 1-3 for alleged indefiniteness. First, the Office Action asserts that the meaning of “nano-calcium phosphates” in claim 1 is unclear. Applicants respectfully traverse. The phrase has a clear meaning (i.e. “calcium phosphate in nanometer scale,” see page 4, lines 21-22). As described on page 4, lines 19 to 22, the collagen matrix of the composite serves as template for mineral nucleation and growth. Calcium phosphate in nanometer scale is uniformly distributed on the matrix.

The Office Action further states that the claim is unclear as to how the defined microstructure level and nanostructure level are related to each other. Applicants have amended the claims to recite that the microstructure level refer the particles which has a specified nanostructure. It is respectfully submitted that this clarification has overcome the rejection. It is further submitted that the claim amendments also adequately address the Examiner's concerns regarding the meaning of "agglomerated particles" and "multiple laminar structure having periodic repeated units." Accordingly, applicants respectfully submit that as amended all pending claims are definite and the rejections under 35 U.S.C. § 112, ¶ 2 should be withdrawn.

Claim Rejections under 35 U.S.C. § 103

The Office Action further rejected all claims under consideration for alleged obviousness over Lee et al., or over Lee et al. in view of Ying et al.. Applicants respectfully traverse. The Office Action essentially asserts that Lee et al. discloses all elements of the presently claimed invention, and those that may not be explicitly described in Lee et al. are inherent therein. Applicants disagree. Lee et al. merely describes bioresorbable ceramic composites. It does not describe or imply that the composite has a nanostructure which mimics that of the natural bone. Even though at column 13, lines 45-51, it suggests that precursors of calcium phosphate may be mixed with the supplementary material, it is merely a generalized description regarding bioresorbable ceramic composites and does not constitute a technical inspiration to explore the composite which mimics the natural bone in structure. There is no evidence that a nano-composite of the present invention is likely to result from the process described in Lee et al., much less that the nano-composite will necessarily result, as the case law on inherency requires. See e.g. *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) ("[The Evidence] must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons in ordinary skill."). In this regard, applicants respectfully submit that the Office Action has not demonstrated that there is any basis in asserting that the procedure of Lee et al. "would have resulted in a composite as presently claimed." Office Action at page 6, lines 22-23. On the other hand, it is the inventors of the present application who found the bio-self-assembling process, that is, under certain conditions calcium phosphates can be formed *in situ* and deposited on the template of acid

Application No. 09/845,724
Reply dated June 16, 2004
Response to Office Action dated January 16, 2004

dissolved collagen so that a composite which mimics natural bone in nanostructure is obtained. Fig. 1A of the present invention shows the nanostructure of the present composite which clearly mimics natural bone as depicted in FIG. 1B.

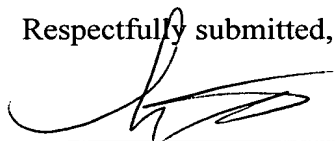
Therefore, applicants respectfully submit that the Office Action has failed to establish a *prima facie* case of obviousness under Lee et al.. The Ying et al. reference does not remedy the deficiency of the primary reference in any way. Furthermore, neither of the two references evinces any motivation that they can be combined, to say less about how they can be modified, so as to arrive at the presently claimed invention, without the hind-sight gathered from the instant disclosure. Therefore, applicants respectfully submit that the obviousness rejection of Claims is improper and should be withdrawn.

In summary, all claims are believed to be in condition for allowance, and applicants earnestly solicit an early indication from the examiner to that effect. If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (CAM # 010313.49928US).

June 16, 2004

Respectfully submitted,



Kening Li, Ph.D.
Registration No. 44,872
J. D. Evans
Registration No. 26,269

CROWELL & MORING LLP
Intellectual Property Group
P.O. Box 14300
Washington, DC 20044-4300
Telephone No.: (202) 624-2500
Facsimile No.: (202) 628-8844
JDE:KL:tlm (010313.49928US; 317078)